

REMARKS

Status of the Claims

Claims 1-3, 6, 8 and 9 are currently pending in the subject application. By this amendment, new Claim 10 has been added, support for which may be found at page 3, lines 3-5, of the filed application. Thus, upon entry of this amendment, claims 1-3, 6 and 8-10 will be pending in the subject application. No new matter has been added.

February 10, 2009 Examiner Interview

Applicants would like to thank Examiners Krishnan and Jiang for the personal interview conducted on February 10, 2009. In compliance with M.P.E.P. § 713.04, the substance of that interview is reflected in the February 10, 2009 Interview Summary and in the following remarks. In the interview, the Examiners preliminarily agreed with Applicants' representative that certain features of the claimed invention were not taught in the art of record.

Double Patenting

Claim 1 stands rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-2 of U.S. Patent No. 7,091,337. Although Applicants traverse this rejection for the reasons of record, Applicants submit herewith a terminal disclaimer with respect to the '337 patent in order to expedite allowance of the subject application. The withdrawal of this rejection is accordingly requested.

Rejections Under 35 U.S.C. §103(a)

Claims 1-3, 6, 8 and 9 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Balazs et al. (*Radiation Research*, 1959, 11, 149-164). Applicants respectfully traverse this rejection.

The invention of amended Claim 1 is a dynamic irradiation process for the depolymerization of heparin wherein the depolymerized heparin has a M_w less than or equal to 50% of the original M_w of said heparin prior to depolymerization, said dynamic irradiation process comprising exposing said heparin in solution at a concentration between 2 and 25% w/v to UV radiation having a peak of from 245 nm to 260 nm for a sufficient time to reduce the M_w

of the depolymerized heparin by at least 50% as compared with the M_w of said heparin prior to said exposure to UV radiation. The subject application defines “dynamic irradiation process” as a process wherein the solution to be irradiated is circulating as a thin layer in a lamp jacket and then returns to a reservoir where it is preferably thermostated. *See* Appl. 10/555,897 at p. 5, lines 8-10.

In contrast to the process of Claim 1 and as conceded in the Office Action, Balazs fails to teach or suggest a dynamic irradiation process in which a solution to be irradiated is circulating as a thin layer in a lamp jacket and then returns to a reservoir. (O/A at p. 6). Instead, Balazs discloses static irradiation in which samples were irradiated in either quartz cells or Teflon containers having silica windows. *See* Balazs at p. 150.

To establish a *prima facie* case of obviousness, all claim limitations must be taught or suggested by the prior art. M.P.E.P. §2143.03; *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). The Office has not cited any reference, however, for teaching or suggesting a “dynamic irradiation process,” i.e., a process wherein the solution to be irradiated is circulating as a thin layer in a lamp jacket and then returns to a reservoir where it is preferably thermostated. For this reason, Applicants respectfully assert that a *prima facie* case of obviousness has not been established with respect to Claims 1-3, 6, 8 or 9, and the withdrawal of this rejection is requested.

Additionally, Balazs fails to teach or suggest the step of exposing said heparin in solution **at a concentration between 2 and 25% w/v** to UV radiation. On the contrary, Balazs operates at a much lower concentrations, i.e., concentrations of about 0.1%. *See* Balazs Fig. 2. According to the Office Action, it is well within the skill level of the artisan to adjust concentrations and process temperatures as routine optimization. (O/A at p. 6). Applicants disagree.

The Balazs reference discusses a study on the degradation effects of UV radiation and electrons on various glycosaminoglycans including heparin. (Balazs at p. 163, Summary). As discussed in the September 29, 2008 Amendment, the Balazs process focuses on **degrading** heparin by exposing it at low concentrations to UV radiation and thereby forming a very high fraction of small fragments. (Balazs Table 1). The resulting small fragments would not be

expected to be biologically active. The presently claimed invention, on the other hand, is directed to *enhancing* heparin—not degrading it—by inherently forming a much lower fraction of small fragments.

In view of the distinctly different purpose of Balazs from that of the claimed invention, one skilled in the art would have no reason whatsoever to modify the teaching of Balazs, as suggested by the Office Action, in order to arrive at the claimed invention. *See W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) (indicating prior art must be considered in its entirety including portions that would lead away from the claimed invention). That is, the Patent Office’s assertion that the claimed invention is obvious over Balazs is improper because it requires wholly disregarding the purpose of Balazs, which expressly teaches away from the presently claimed invention. For this reason also, Applicants assert that the rejection of the claimed invention in view of Balazs should be withdrawn.

In addition, secondary evidence of record supports the patentability of the claimed invention. As indicated in the De Ambrosi Declaration, submitted with the September 29, 2008 Response, the processes of the present invention, in stark contrast to the Balazs processes, inherently form fragments having a Mw less than 1000 Da in an amount less than 6%, even when the overall Mw has been reduced to less than 5000 Da. (De Ambrosi Decl. at ¶ 13). This surprising and unexpected result is strong evidence of the non-obviousness of the presently claimed invention. *See id.* at ¶ 14.

For the foregoing reasons, Applicants respectfully assert that pending Claims 1-3, 6 and 8-10 are in condition for allowance over the references of record, and a Notice thereof is respectfully requested.

Conclusion

Should the Examiner have any questions regarding this response or the application in general, the Examiner is urged to contact the Applicants' attorney, Justin L. Krieger, by telephone at (202) 625-3858. All correspondence should continue to be directed to the address given below.

Respectfully submitted,

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